Serial No.: 10/631,318 -7 - Art Unit: 3762

Conf. No.: 1899

REMARKS

Claim 2 has been amended to recite that the pre-polymeric material can be polymerized by applying heat and/or radiation. Support for this amendment can be found through out the specification, for example on page 13, lines 26-27.

Claims 2-42 are currently pending.

The Priority Claim

The Patent Office has not given the instant application the benefit of the priority chain as claimed by the Applicants, and the Examiner has suggested a review of the chain of priority listed in U.S. Patent No. 6,699,272.

Previously, the Patent Office issued a notice on January 29, 2004 stating that a prior-filed application, to which the instant application claims priority to, had been improperly indicated as a National Stage Application. Applicants believe this notice to be in error, and believe the priority claim as presented in the application to be correct. On March 31, 2004, Applicants filed a Request for Corrected Filing Receipt which included evidence that Application Serial No. 07/651,346 (which the instant application claims priority to) was the National Stage Application under 35 U.S.C. §371 of PCT/US89/03593, as indicated by a copy of the Request for Entry into the National Stage under 35 U.S.C. §371 of PCT/US89/03593, and a copy of the corresponding Filing Receipt which indicated that the entry into the National Stage was granted and that the application was given Serial No. 07/651,346. Applicants also submitted a copy of Patent No. 6,699,272, in which the priority claim includes 07/651,346 as the National Stage filing of PCT/US89/03593.

Applicants have not yet received a corrected filing receipt from the Patent Office. Thus, Applicants respectfully repeat their request that the correction to the priority claim be made, and a corrected filing receipt be issued. It is believed, that upon issuance of a corrected filing receipt by the Patent Office pursuant to the above-noted Request, the concerns described by the Examiner will have been addressed.

Serial No.: 10/631,318 - 8 - Art Unit: 3762

Conf. No.: 1899

Rejections under 35 U.S.C. §102(b) in view of Spears

Claims 2-9, 12-17, 28, 30, 32, and 37-42 have been rejected under 35 U.S.C. §102(e) as being anticipated by Spears, U.S. Patent No. 5,092,841 ("Spears").

Applicants believe that issuance of the corrected filing receipt as discussed above will indicate that Spears is not applicable as a reference to the instant invention. Accordingly, Applicants respectfully defer addressing the merits of the rejection in view of Spears until later in prosecution, if necessary.

Rejections under 35 U.S.C. §102(b) in view of Polin

Claims 2, 6, 9, 14, 37, 40, and 42 have been rejected under 35 U.S.C. §102(b) as being anticipated by Polin, U.S. Patent No. 3,949,068 ("Polin").

Applicants do not see where in Polin is there a disclosure or suggestion of polymerizing pre-polymer material on a tissue surface to form thereon a layer of a polymeric, non-fluent material. Instead, Polin describes a liquid, surrounded by a membrane, that is injected into an animal. For example, in column 1, lines 8-20, Polin states that his invention relates to "the controlled release of a drug," and that "This is accomplished by the injection of a coated or enrobed solution whereby the drug diffuses slowly through a liquid or plastic membrane. More specifically, injectables suitable for animal use are stabilized by the process of enrobing the active ingredient in solution form with a liquid envelope [such that] it provides a continuous external phase and so results in a controlled or reduced and constant rate of diffusion of the active ingredient through the membrane." Thus, the "membrane" referred to in Polin surrounds the liquid containing the drug, and therefore is not a layer of a polymeric, non-fluent material on a tissue surface. It is not seen how such materials "will inherently modulate the tissue by providing a barrier and providing drug delivery," as the materials form a barrier on the injected liquid, not on tissue.

Accordingly, it is believed that claim 2 is not anticipated by Polin, and is respectfully requested that the rejection of claim 2 be withdrawn. Claims 6, 9, 14, 37, 40, and 42 each depend, either directly or indirectly, from claim 2, and are believed to be patentable for at least the same reasons. Withdrawal of the rejection of these claims is also respectfully requested.

Serial No.: 10/631,318 - 9 - Art Unit: 3762

Conf. No.: 1899

Rejections under 35 U.S.C. §102(b) in view of Hettinger

Claims 2, 6, 10, 14, 15, and 40-42 have been rejected under 35 U.S.C. §102(b) in view of Hettinger, U.S. Patent No. 4,371,519 ("Hettinger").

Applicants do not see where Hettinger discloses or suggests polymerizing a prepolymeric material on a tissue surface by applying heat and/or radiation. Thus, it is believed that claim 2, as amended, is patentable in view of Hettinger. It is respectfully requested that the rejection of claim 2 be withdrawn. Claims 6, 10, 14, 15, and 40-42 depend, directly or indirectly, from claim 2, and are believed to be allowable for at least the above-mentioned reasons. The withdrawal of the rejection of these claims is also respectfully requested.

Rejections under 35 U.S.C. §103(a) in view of Spears

Claims 10, 11, 18-27, 29, 31, and 33 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Spears.

As discussed above, Spears is believed to be inapplicable as a reference. Accordingly, Applicants respectfully defer addressing the merits of the rejection in view of Spears until later in prosecution, if necessary.

Rejections under 35 U.S.C. §103(a) in view of Polin

Claims 3-5, 7, 8, 10-13, 15-36, 38, 39, and 41 have been rejected under 35 U.S.§103(a) as being unpatentable over Polin.

Claims 3-5, 7, 8, 10-13, 15-36, 38, 39, and 41 each depend, either directly or indirectly, from claim 2. For at least the reasons explained above with respect to the rejection under §102(b) in view of Polin, the premise of the rejection of claim 2 (that Polin teaches all of the limitations of claim 2) is believed to be incorrect. Accordingly, while Applicants do not concede that there would have been any suggestion or motivation to make the modifications as suggested in the Office Action, the present rejection cannot stand, regardless. Thus, withdrawal of the rejection of claims 3-5, 7, 8, 10-13, 15-36, 38, 39, and 41 is respectfully requested.

Serial No.: 10/631,318 - 10 - Art Unit: 3762

Conf. No.: 1899

Rejections under 35 U.S.C. §103(a) in view of Hettinger

Claims 3-5, 7-9, 11-13, and 16-39 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Hettinger.

Claims 3-5, 7-9, 11-13, and 16-39 each depend, either directly or indirectly, from claim 2. For at least the reasons explained above with respect to the rejection under §102(b) in view of Hettinger, the premise of the rejection of claim 2 (that Hettinger teaches all of the limitations of claim 2) is believed to be incorrect. Accordingly, while Applicants do not concede that there would have been any suggestion or motivation to make the modifications as suggested in the Office Action, the present rejection cannot stand, regardless. Thus, withdrawal of the rejection of claims 3-5, 7-9, 11-13, and 16-39 is respectfully requested.

Double Patenting Rejections

Claims 2-42 have been rejected under the judicially-created doctrine of obviousness-type double-patenting as being unpatentable over claims 1-35 of U.S. Patent No. 6,443,941 and 1-24 of U.S. Patent No. 5,575,815. However, the Patent Office stated that a timely filed Terminal Disclaimer in compliance with 37 C.F.R. §1.321(c) may be used to overcome this rejection.

Without acceding to the correctness of this rejection, enclosed herewith are Terminal Disclaimers with respect to U.S. Patent Nos. 6,443,941 and 5,575,815 in compliance with 37 C.F.R. §1.321(c). In view of these Terminal Disclaimers, claims 2-42 are believed to be allowable. Withdrawal of the rejection of these claims is therefore respectfully requested.

Serial No.: 10/631,318 - 11 - Art Unit: 3762

Conf. No.: 1899

CONCLUSION

In view of the foregoing remarks, this application should now be in condition for allowance. A notice to this effect is respectfully requested. If the Examiner believes, after this response, that the application is not in condition for allowance, the Examiner is requested to call the Applicants' representatives at the telephone number listed below.

If this response is not considered timely filed and if a request for an extension of time is otherwise absent, Applicants hereby request any necessary extension of time. If there is a fee occasioned by this response, including an extension fee, that is not covered by an enclosed check, please charge any deficiency to Deposit Account No. 23/2825.

Respectfully submitted,

By:

Timothy J. Oyer, Mh.D., Reg. No. 36,628

Tani Chen, Sc.D., Reg. No. 52,728 Wolf, Greenfield & Sacks, P.C.

600 Atlantic Avenue

Boston, Massachusetts 02210-2206

Telephone: (617) 646-8000

Docket No.: F0397.70068US00 Date: September 24, 2004

x09/24/04x